

AMENDMENTS TO THE SPECIFICATION

Please replace the entire section of the specification following the title and through page 6 of the specification with the following:

This invention relates to ~~radiation applicator~~microwave radiators and, in particular, to microwave ablation devices.

A known ~~radiation applicator~~microwave radiator, used for microwave ablation of tissue, comprises a microwave generator operatively coupled to an elongate waveguide for conveying the microwaves to the ablation site. The waveguide is sufficiently thin to be inserted into the body and contains a core of dielectric material which enables efficient transmission of microwaves through the waveguide. At the emission end of the waveguide, the dielectric core protrudes and provides a radiating tip for coupling microwaves into surrounding tissue. An object of the inventor is to provide an improved radiator.

According to one aspect, the invention ~~consists in~~includes an elongate ~~device~~microwave radiator for insertion into a living body, ~~the device having an antenna at its tip for coupling radiation into biological matter and a dielectric body surrounding the antenna so as to encompass substantially the whole of of the near field of the radiation emitted by the antenna to treat biological tissue at a predetermined operating frequency, the radiator comprising a monopole at its tip and dielectric material surrounding the monopole; characterised in that said dielectric material is adapted so that it acts as a resonator at said predetermined operating frequency, and encompasses generally the whole of the near-field radiation emitted by the monopole.~~

The invention is based on an appreciation of the fact that ~~the~~a monopole antenna generates a near-field, and that the near-field contains large field amplitudes which exist quasi-statically in the local region of the ~~antenna~~monopole and do not radiate energy. In a normal communications antenna, this local region is air-filled and these near-field amplitudes have no effect except to contribute reactance to the antenna impedance. However, in a medical application, if the near-field region contains biological matter, which is highly lossy, the near-field amplitudes will generate heat.

Because of the high amplitudes and small volume of the near-field region, much heat can be generated in the near-field region, which reduces the energy in the far-field. Field penetration is therefore reduced, and local charring in the near-field region becomes a limiting factor in the power that can be input to the antenna.

The dielectric body according to the invention serves to provide a low loss environment to encompass the near-field region so that more power is transmitted to the biological matter in the far-field region.

The extent of the near-field is determined by the wavelength  $\lambda$  of the radiation in the dielectric and the ~~major dimension~~length  $L$  of the ~~antennamonopole~~ according to the relationship  $2L^2/\lambda$ . ~~Furthermore, in an antenna,  $L$  is proportional to  $\lambda$ .~~ The extent of the near-field therefore is proportional to  $\lambda$ , and it is possible to reduce the extent of the near-field region by increasing the dielectric constant of the body to reduce the wavelength of the radiation within it. The overall external dimension of the device can therefore be reduced for insertion into a living body. A higher dielectric constant will also accommodate the use of lower frequency radiation, which would otherwise increase the wavelength and the extent of the near-field; the lower frequency radiation being beneficial in increasing radiation penetration into the far-field.

A monopole antenna, for good impedance matching, has  $L$  generally equal to  $\lambda/2$ . By substitution in the above relationship, the extent of the near-field is then equal to  $\lambda/2$ , and this determines the minimum extent of the dielectric material. Furthermore, a  $\lambda/2$  dimension for the dielectric material is consistent with its operation as a resonator to ensure that the radiator is effective in transmitting radiation at the required power levels for the treatment of biological material.

In one embodiment of the invention, the dielectric body comprises a cylindrical shape with the ~~antennamonopole~~ extending axially along its ~~centre~~center a distance  $L$ , ~~with the radius of the cylinder being substantially equal to  $2L^2/\lambda$ .~~ A ~~device~~radiator of this kind can be designed with a minimum radius for insertion into biological matter, such as a liver, and will create an annular

radiation field around it. A pointed tip may be provided at the free end of the dielectric material to assist penetration of biological matter.

~~The length L of the antenna may be substantially equal to half a wavelength, in which case the radius of the cylindrical dielectric body is substantially equal to half a wavelength. The antenna is then tuned to act as a resonator, which increases the power it radiates.~~

~~However,~~ as the dielectric constant is increased, it may exceed that of the biological matter, which can lead to total internal reflection of radiation within the dielectric and a consequent reduction in transmitted radiation. In order to overcome this problem, the dielectric body is formed so that the dielectric constant at its core is higher than that at its outer periphery, the latter having a value intermediate that of the core and the biological matter. Thus, the dielectric constant at the core may be higher than that of the surrounding biological matter so as to help reduce the overall diameter of the device radiator. The different dielectric constants may correspond to different layers of dielectric, each with a different dielectric constant, or may correspond to different levels in a dielectric in which the dielectric constant varies throughout its depth.

According to another aspect, the invention ~~consists in~~ includes an elongate ~~device~~ microwave radiator for insertion into a living body, ~~the device having an~~ to treat biological tissue at a predetermined operating frequency, the radiator comprising a monopole antenna at its tip for ~~coupling radiation into biological material and a dielectric body and dielectric material surrounding and extending beyond the monopole antenna so as to enhance;~~ characterised in that said dielectric material terminates in a rounded tip portion and is adapted so that it acts as a resonator at said predetermined operating frequency and enhances transmission of radiation in the forward direction.

Preferably, ~~the dielectric body completely envelops the antenna and has a tip portion that extends beyond the end of the antenna to support internal reflection of the radiation in the forward direction. Advantageously, the dielectric body is tuned to act as a resonator to further enhance radiation from the tip of the elongate device in the insertion direction. In particular, the diameter~~

~~of the dielectric body is substantially equal to the wavelength of the radiation, and the tip portion~~  
is ~~substantially~~generally hemispherical and has a radius ~~substantially~~generally equal to half a wavelength of the radiation in the dielectric material.

The ~~elongate device radiator~~ may further comprise a coaxial conductor (preferably packed with a dielectric) which supplies radiation to the monopole antenna from a radiation generator. Preferably, the ~~antennamonopole~~ then comprises an exposed length of the central conductor of the coaxial conductor at its distal end. Preferably, the exposed length of the central conductor providing the ~~antennamonopole~~, is ~~substantially~~generally half ~~athe~~ wavelength ~~long~~ of the radiation in the dielectric. The coaxial conductor may be rigid or a flexible cable.

Preferably, the dielectric ~~body~~material has a dielectric constant, or relative permittivity, such that the length of the ~~antennamonopole~~ is reduced. Advantageously, there can be a transformer between the coaxial conductor and the dielectric ~~body~~material to reduce reflection of radiation back into the coaxial conductor from the boundary between it and the dielectric ~~body~~material. Such a transformer can advantageously contain a space into which the dielectric packing of the coaxial conductor can expand.

According to yet another aspect, the invention includes methods of coupling radiation into biological material using the devices according to the invention.

Further advantages and features of the invention will become apparent to readers skilled in the art upon consideration of the following description of embodiments of the invention, the embodiments being described by way of example only, and with reference to the accompanying figures, in which:

Figure 1 shows a first embodiment of a radiator according to the invention;

Figure 2 shows the tip section of a radiator of Figure 1 in more detail;

Figure 3 shows a second embodiment of the tip section of the radiator incorporating a transformer;

Figure 4 shows a third embodiment of the radiator;

Figure 5 shows the tip of the radiator of Figure 4; and

Figure 6 shows a side-elevation of a variation in design of the radiator of Figure 4.

Figure 1 shows the general arrangement of the microwave radiator 100. A radiation generator 110, for example, a microwave generator, produces radiation which is coupled into coaxial cable 120 which transmits the radiation to a distal tip region 130 at which there is an antenna for emitting the radiation into the material surrounding the tip 130. In use, the coaxial cable 120 is introduced into a living body and the tip 130 is positioned adjacent a region which it is desired to irradiate. For example, the device could be inserted into an artery to irradiate plaques on the walls thereof or the device could be introduced into a uterus to irradiate the endometrium. The supply of radiation is controlled by a control device 140, often a foot pedal, which is used to signal the microwave generator to begin, adjust or stop the supply of radiation to the tip 130.

Figure 2 shows the tip region 130 of the radiator of figure 1 in more detail. The tip region, generally indicated 200, shows the distal end of the coaxial cable which comprises an outer conductor 210 spaced from a core conductor 220. The space between the conductors 210 and 220 is filled with a dielectric material 230. The antenna for emitting radiation conducted by the cable comprises a length 240 of the core conductor of the coaxial cable extending beyond the outer conductor 210 at the distal end of the coaxial cable to form a monopole. To enhance the radiating qualities of the ~~antenna~~ monopole 240, it is preferred that ~~the~~ its length of core conductor ~~providing the antenna~~ is about one half of a wavelength of the radiation in the dielectric. The ~~antenna~~ monopole 240 is enveloped by dielectric body 250 in which the wavelength of the employed radiation is reduced below its free-space value hence enabling the ~~exposed length 240 of the core conductor providing the antenna~~ monopole to be shorter than might otherwise be possible. ~~In order to enhance radiation from the antenna in~~

~~the forward direction, the~~ The dielectric body 250, ~~in addition to comprising~~ comprises a cylindrical portion 260 which envelops the ~~exposed length of core conductor~~ monopole 240. The diameter of the cylindrical portion 260 is generally equal to the wavelength of the radiation in the dielectric at the operating frequency so that it is tuned to act as a resonator to increase the power it radiates. Also, the dielectric body comprises a hemispherical section 270 which supports partial internal reflection of the radiation from the antenna in the forward direction as indicated by arrows 280 and 290. The hemispherical section 270 is dimensioned so as to provide a resonator which further enhances radiation from the dielectric body in 250 in the forward direction. Resonance of radiation partially reflected within the dielectric body 250 can be encouraged by, for example, dimensioning the hemispherical section 270 to have a radius approximately equal to one half of a wavelength of the radiation employed. It will be appreciated that the dielectric body can have other dimensions and shapes provided that they encourage forward propagation of the radiation by means of internal reflection and/or resonance.

When this equipment is to be used for endometrial ablation it is desirable to use radiation having a frequency around 9.2GHz. In free-space, the wavelength of such radiation is about 32mm. Using dielectric material with, for example, a dielectric constant  $\epsilon_R=25$  reduces the wavelength to about 6mm. Correspondingly, the diameter and overall length of the dielectric material are then also about 6mm.

Figure 3 shows an alternative embodiment of the tip section of the radiator, generally indicated 300. Here, in order to reduce reflection of radiation from the coaxial cable at the boundary between it and the dielectric material, a transformer 310 is incorporated between the coaxial cable and the dielectric material. The transformer 310 comprises several sections (for example, three: 320, 330, 340) of cylindrical shape and of successively increasing radius towards the dielectric material. Advantageously, at least the section 320 of the transformer adjacent the coaxial cable does not contain a solid filler material. This provides the benefit that, when the radiator is heated, for example in manufacture or in use, the dielectric packing filling the space between the core and outer conductors of the coaxial cable can expand into the transformer thus relieving otherwise deleterious pressures.

The near-field radiation generated by the radiator of Figures 2 and 3 extends from the ~~antennam~~antennamonopole 240 a distance determined by the formula  $2L^2/\lambda$ , where L is the ~~exposed~~ length of the ~~antennam~~antennamonopole, and  $\lambda$  is the wavelength of the radiation in the dielectric material 250. However, the preferred value of L is  $\lambda/2$ , and therefore the near-field radiation is contained within a region of radius  $\lambda/2$  about the ~~antennam~~antennamonopole. Therefore, the near-field radiation does not extend into the more lossy biological material that surrounds the radiators in use, and the resulting detrimental affects of local charring and reduction of radiation penetration are reduced or avoided. Instead, the microwave power is emitted into the far-field to increase penetration and power transfer.

Figure 4 shows yet another embodiment of the invention in which a generator 310 supplies microwave energy via a rigid coaxial conductor 320 to a tip region at the distal end of the conductor. Dielectric packing 330 is provided between the inner and outer conductors of the coaxial conductor 320. As shown in more detail in Figure 5, a length of the inner conductor 340 at the tip is exposed by removal of the outer conductor so as to form an ~~antennaa~~antennaa monopole to emit radiation. The ~~antennam~~antennamonopole 340 is embedded axially in a cylindrical body of dielectric 350 which has substantially the same outer diameter as the coaxial conductor 320. A pointed metal tip 370 is fixed to the end of the dielectric 350 and serves to assist penetration into biological matter, such as a liver to perform ablation on a tumour. The ~~antennam~~antennamonopole 340 preferably has a length substantially equal to half a wavelength of the radiation in the dielectric, and the radius of the dielectric body 350 is also preferably substantially equal to half a wavelength of the radiation in the dielectric. The near-field radiation emitted by the ~~antennam~~antennamonopole will then lie within a region  $2L^2/\lambda$ , which is equal to a radius of half of the wavelength of the radiation in the dielectric so that the near-field lies substantially totally within the dielectric. The dielectric constant of the dielectric body is selected to be high so as reduce losses within the dielectric. The microwave energy is therefore emitted into the far-field region in an annular pattern around the tip so as to increase field penetration and power transfer. Typically, a radiation applicator used with a generator operating at 10 GHz and having a dielectric body with dielectric constant  $\epsilon_R=25$ , will have a dielectric body radius of 3 mm. Because the radius of the dielectric body 350 is substantially

equal to half a wavelength, it is tuned to act as a resonator, which increases the power it radiates.